

K120847

510(k) Summary

AUG 10 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: March 16, 2012

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804, Republic of Korea
- Contact :	Mr. Hee Kwon Son
- Phone:	+82 51 850 2575
- Correspondent's Name:	HIOSSEN Inc.
- Address:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact:	Patrick Lim
- Phone:	888 678 0001

2. Device :

Trade or (Proprietary) Name :	ET/SS Implant System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device:

The HU II / HS II Fixture System, Osstem Implant Co., Ltd, K080387
The ET III SA Fixture System, HIOSSEN Inc., K101096
The HS II Short Fixture System, Osstem Implant Co., Ltd, K083633
The Prosthetic System, Osstem Implant Co., Ltd., K110308
The Ziocera & Convertible System, Osstem Implant Co., Ltd., K081786
The HU.HS.HG Prosthetic System, Osstem Implant Co., Ltd., K081575

4. Description:

The ET/SS Implant System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.

Fixture is made of pure titanium metal and supplied sterile. The surface is SA, Sandblasting and Acid etching, treated.

Abutment is device made of titanium alloy intended for use as an aid in prosthetic restoration. It consists of Abutments and Abutment Screws. Its surfaces are partially Tin coated and uncoated

The ET/SS Implant System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

The ET/SS Implant System is substantially equivalent in design, function and intended use to the HU II / HS II Fixture System (K080387) of Osstem Implant Co., Ltd., the ET III SA Fixture System (K101096) of HIOSSEN Inc. and the HS II Short Fixture System (K083633) of Osstem Implant Co., Ltd,

The Prosthetic System such as abutment and cylinder in the ET/SS Implant System is substantially equivalent in design, function and intended use to the Prosthetic System (K110308) of Osstem Implant Co., Ltd, The Ziocera & Convertible System(K081786) of Osstem Implant Co., Ltd and The HU.HS.HG Prosthetic System(K081575) of Osstem Implant Co., Ltd.

- Substantial Equivalence Matrix

	ET/SS Implant System (SSII/III SA Fixture)	Predicate devices		
		HS II Fixture (K080387)	ETIII SA Fixture (K101096)	HS Short Fixture (K083633)
Design				
Intended use	ET/SS Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or	HS II Fixture System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained,	ETIII SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw	HS II Short Fixture System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or

	overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.	screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. It is not for immediate load	retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The ETIII SA Fixture System is for single and two stage surgical procedures. It is not for immediate load. The Ultra wide Fixture System is intended to be used in the molar region.	overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. It is not for immediate load
Surgery type	One and two stage Surgery	One and two stage Surgery	One and two stage Surgery	One and two stage Surgery
Structure	- Non Submerged Fixture - Self tapping - Internal Octagonal connection - Straight Body	- Non Submerged Fixture - Self tapping - Internal Octagonal connection - Straight Body	- Submerged Fixture - Self tapping - Internal Hexagonal connection - Taper Body	- Non Submerged Fixture - Straight Body Type - Self tapping - Internal Octagonal connection
Platform (D)	4.8~6.0	3.5~6.0	N/A	5.0~7.0
Body Diameter (D)	4.1~4.9/3.75~5.0	3.5~5.0	3.5~5.0	4.95 ~ 6.85
Length (mm)	6~15.0	8.5~15.0	7.0~15.0	6.0
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA	RBM	SA	RBM
Packaging	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	5years	3 years	5 years	5 years
S E	SSII/III SA Fixture has the same material, indication for use and similar design as the HSII Fixture in the HU II / HS II Fixture System (K080387) except surface treatment. but the surface treatment of SS SA Fixture is the same with surface treatment of ETIII SA Fixture System (K101096)			

5. Indication for use :

The ET/SS Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with



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a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.

6. Review :

The ET/SS Implant System has same material and indication for use and similar design and technological characteristics as the predicate device.

The ET/SS Implant System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing

The Fatigue testing was conducted according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” and ISO 14801 Dentistry - Fatigue test for endosseous dental implants with the worst case scenario. The results are in compliance with it and were similar to previously cleared predicate devices.”

8. Summary of clinical testing

No clinical studies are submitted

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that the ET/SS Implant System is substantially equivalent to the predicate devices as described herein



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OSSTEM Implant Company, Limited
C/O HIOSSEN, Incorporated
Mr. Patrick Lim
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

AUG 10 2012

Re: K120847

Trade/Device Name: ET/SS Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 29, 2012
Received: July 11, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

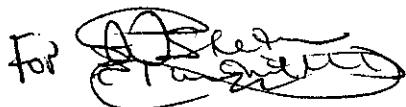
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson". To the left of the signature, the word "For" is written vertically.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Number K _____

Device Name : ET/SS Implant System

Indication for use : The ET/SS Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.

Prescription Use X
(Per 21CFR801 Subpart D)

OR Over-The-Counter Use _____
(Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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